

### Remarks

Upon entry of the Amendment claims 41, 42 and 53 are pending in the application. Claim 41 has been amended and claim 53 added. Support for the amendment is found at page 15, line 31 through page 16, line 5, and in Figures 1-5. Applicants respectfully submit that no new matter is added by the amendment.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) over Cerami et al. (WO 99/44583) in view of Sternick et al. (WO 85/03635). Applicants respectfully traverse.

The PTO has the burden under section 103 of establishing a *prima facie* case of obviousness. Applicants respectfully submit that three criteria must be met in order to satisfy this burden. First, there must be some objective suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all claim limitations.

The rejection appears to be based on the premise that fibers as disclosed in Sternick may be used to replace the sponge scaffold in immune modulation devices of Cerami. Applicants respectfully submit that there is no suggestion or teaching in Sternick that would motivate one skilled in the art of immune modulation devices to modify the fibers mentioned in Sternick to provide “textured” yarns as claimed by Applicants that include crimped fibers that contain crimp points, as claimed by Applicants, for use in Applicants’ devices. The only mention of fibers in Sternick is found at page 4, lines 24, where it is stated that glass fiber filters, cotton fibers, and nylon mesh filters may be used as an alternate to preferred nitrocellulose filter disks as substrates. There is no suggestion that fibers should be “textured” or otherwise treated or modified in any way when used in immune modulation devices.

As the combination of Cerami and Sternick then fails to teach or suggest all claim limitations of claim 41 or 42, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claim 41 or 42. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 41 and 42 under 35 U.S.C. 103(a) over Cerami et al. in view of Sternick.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) over Cerami et al. (WO 99/44583) in view of Li et al. (6,303,136). Applicants respectfully traverse

Applicants initially respectfully submit that there is no suggestion in Cerami or Li that would motivate one skilled in the art of preparing immune modulating devices to replace the sponge scaffolds of Cerami with fibers as disclosed in Li, with the reasonable expectation of success that such fibers would be useful in immune modulating devices claimed by Applicants.

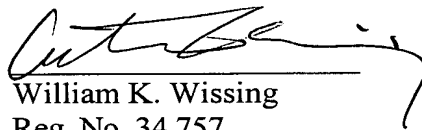
Secondly, assuming *arguendo* that there is motivation to use the fibers of Li in the devices of Cerami, Applicants respectfully submit that there is no suggestion or teaching that would motivate one skilled in the art of immune modulation devices to modify the fibers of Li to provide “textured” yarns as claimed by Applicants that include crimped fibers that contain crimp points, as claimed by Applicants, for use in Applicants’ devices. As can be seen by comparing Figure 2 of Applicants’ specification and Figure 2 of Li, fibers disclosed in Li are not crimped and do not include crimp points where the orientation of filaments in the fibers changes angles. The only mention of “texturized” fibers in Li is found at column 5, lines 24-26, where it is stated that “filaments may be “texturized” to provide rough surfaces and “hand holds” onto which cell projections may attach”. Applicants respectfully submit that this statement alone suggests only “roughened” fibers and does not suggest “textured” yarns as claimed by Applicants.

As the combination of Cerami and Li then fails to teach or suggest all claim limitations of claim 1, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claim 1 and claims depending thereon. Therefore, Applicants

respectfully request reconsideration and withdrawal of the rejection of claims 41 and 42 under 35 U.S.C. 103(a) over Cerami et al. in view of Li et al.

Applicants respectfully submit that this is a complete response to the Office Action and that all pending claims are patentable. Accordingly, Applicants respectfully request a notice of allowance to that affect. Should the Examiner be of the opinion that the pending claims are not patentable in view of the above, Applicants request a telephonic interview with the Examiner to discuss the Amendment and arguments set forth herein. Applicants' representative may be reached from 9:00 a.m. to 5:00 p.m. on Mondays and Thursdays at 908-218-3389 and on Tuesday, Wednesday and Friday at 732-524-6201. Applicants wish to express their appreciation in advance for the courtesy to speak with the Examiner.

Respectfully submitted,



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